K000717

Section V

MAR 3 0 2000

510(k) Summary
Special 510(k):
Date Prepared: February 29, 2000

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc., Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

B. Company Contact

Nicholas Condakes
Regulatory Affairs Specialist

C. Device Name

Trade Name: Smith & Nephew SutureLok
Common Name:

- Suture Retention Device
- Endoscope Accessory
- Laparoscope Accessory

Classification Name:

- Suture Retention Device (KGS)
- Endoscope Accessory (GCJ)
- Laparoscope Accessory (HET)

D. Predicate Devices

The Smith & Nephew SutureLok is substantially equivalent in design, materials, function and intended use to the following devices in commercial distribution:

Smith & Nephew SutureLok-K991500

E. Description of Device

The Smith & Nephew SutureLok comprises three main components:

- The suture Lok implant (ring and pin)
- The disposable cartridge assembly with threader, and
- The reusable delivery instrument

F. Indications for Use

The Smith & Nephew SutureLok is indicated for use in open and endoscopic procedures, including thoracoscopic surgery, laparoscopic procedures and general surgery. The device is not indicated for use in contraception tubal ligation.

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G. Intended Use

The Smith & Nephew SutureLok is intended for use in conjunction with USP size 0, 2-0 and 3-0 braided silk, nylon or polyester non-absorbable sutures in the management of soft vessel ligation and/or fixation of soft tissue structures during open and endoscopic procedures.

H. Comparison of Technological Characteristics

The Smith & Nephew SutureLok is identical to the predicate device in its intended use, and similar in safety and effectiveness. The only difference between the new implant and the predicate device is that the Lock Ring outside diameter is redesigned to add a titanium sleeve and to increase distal end material thickness.

Comparative strength testing demonstrated the equivalence of the SutureLok to the predicate device.

Nicholas Condakes

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Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2000

Mr. Nicholas Condakes
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover , Massachusetts 01810

Re: K000717
Trade Name: SutureLok
Regulatory Class: II
Product Code: KOG
Dated: February 29, 2000
Received: March 3, 2000

Dear Mr. Condakes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement K000717

510(k) Number
(if known)

Device Name Smith & Nephew SutureLok

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MRO for CMD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000717

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR § 801.109)